ucb Pharma
UCB Pharma, Inc. - 1950 Lake Park Drive - Smyrna, Georgia 30080

March 22, 1999

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 98N-0182:
Comments on Proposed Rule – "List of Bulk Drug Substances That May Be Used in Pharmacy Compounding"

Dear Sir or Madam:

UCB Pharma, Inc. herewith provides comments to the Federal Register Proposed Rule of Thursday, January 7, 1999 [Docket no. 98N-0182] entitled, "List of Bulk Drug Substances That May Be Used in Pharmacy Compounding". Specifically, UCB Pharma, Inc. will address the inclusion of piracetam on the Nominated Drug Substances Being Proposed for Inclusion on the Bulk Drugs List included under section 503A(d)(2) of the Federal Food, Drug, and Cosmetic Act.

Piracetam, the active ingredient of NOOTROPIL® was registered by UCB S.A., Pharma Sector in Belgium in 1972. UCB Pharma, Inc. is a wholly owned subsidiary of UCB S.A. Piracetam is currently marketed by UCB S.A. Pharma Sector in 87 countries worldwide.

During the last few years NOOTROPIL® has been evaluated by health authorities in several European countries. Simultaneously, UCB S.A. Pharma Sector has sponsored controlled clinical trials in Europe which demonstrate that piracetam is effective in the treatment of myoclonus. NOOTROPIL® received approval as an add-on treatment for

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cortical myoclonus in the United Kingdom in December of 1992 and most recently in Sweden in December of 1997. Piracetam is marketed in 21 countries for myoclonus, including 10 Western European countries. On March 31, 1998, UCB Pharma, Inc. submitted a New Drug Submission (NDS) for piracetam in the treatment of myoclonus of cortical origin to the Canadian Health Protection Branch. Currently, the NDS has passed the preliminary review period and is now in full review.

On October 2, 1987, UCB Pharma Inc. received Orphan Drug designation (#87-209) for piracetam in the treatment of the rare condition myoclonus. Currently, UCB Pharma Inc. is in the process of finalizing a double blind, placebo controlled study protocol to further demonstrate the safety and efficacy of piracetam as adjunctive therapy in the treatment of myoclonus in the U.S.

The IND status of the list of proposed drugs was discussed at the Pharmacy Compounding Advisory Committee meeting held on October 14-15, 1998. In this meeting, Mr. Tonelli of the Center for Drug Evaluation and Research stated, "I would just like to point out that none of these would be excluded from the IND procedures, and we can always entertain an IND for any of these products". Additionally, Ms. La Follete replied with "I would concur. If an IND is already in process I don't think this Committee should be addressing this drug. It should be removed."

UCB Pharma, Inc. is in agreement with this position. The IND process is intended to allow pharmaceutical companies an instrument by which human clinical trials can be carried out in indications of medical need. According to the minutes of the Pharmacy Compounding Advisory Committee, piracetam was described to be "believed by some to enhance certain cognitive skills, and has been used to treat Down's Syndrome, dyslexia, and Alzheimer's disease, among other cognitive disorders". However, clinical data supporting efficacy in these indications is limited.

UCB Pharma, Inc. intends to develop piracetam in the U.S. as treatment for myoclonus, an orphan drug indication for which there are controlled clinical trials providing compelling efficacy data. Listing piracetam on the pharmacy compounding list would interfere with clinical trials planned in the U.S. Myoclonus patients are aware of the efficacy of the treatment and if piracetam is readily available through pharmacy compounding, these patients will have no reason to enroll in a controlled clinical study.

The development of piracetam in the U.S. offers many benefits to the public health. Most importantly, the clinical study will provide confirmatory evidence of efficacy in myoclonus, an orphan drug indication for which there is clearly an unmet medical need. The product labeling and package insert would provide accurate and up-to-date information for use by the consumer, physician and pharmacist. Furthermore, the quality of the product will be assured though the application of Good Manufacturing Practices.

In closing, from a public health perspective, the most responsible means for availability of piracetam is through the mechanisms established by the Agency to ensure safety and efficacy of all new drugs to the public. Therefore, UCB Pharma, Inc. formally requests that piracetam be removed from the List of Bulk Drug Substances That May Be Used in Pharmacy Compounding.

Sincerely,

Patricia Fritz
Director, Regulatory Affairs

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